



DOCKET NO.: S1383.70011US00

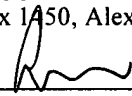
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Blumberg et al.
Serial No.: 10/622,108
Confirmation No.: 5945
Filed: July 17, 2003
For: CENTRAL AIRWAY ADMINISTRATION FOR
SYSTEMIC DELIVERY OF INTERFERON ALPHA

Examiner: Unknown
Art Unit: 1614

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 25th day of November, 2003.



Alan W. Steele, M.D., Ph.D., Reg. No. 45,128

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

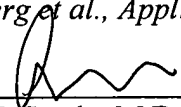
Transmitted herewith are the following documents:

- ☒ Supplemental Information Disclosure Statement Under 37 C.F.R. §1.56, 1.97 & 1.98
- ☒ Form PTO-1449 with References Cited
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617)720-3500, Boston, Massachusetts.

No fee is believed to be due. If a fee is required, The Commissioner is hereby authorized to charge the amount to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Blumberg et al., Applicant

By: 

Alan W. Steele, M.D., Ph.D., Reg. No. 45,128
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
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Telephone: (617) 720-3500

Docket No.: S1383.70011US00
Date: November 25, 2003
xNDDx



DOCKET NO.: S1383.70011US00

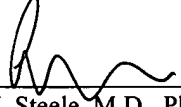
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Alan W. Steele, M.D., Ph.D., Reg. No. 45,128

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case. No fee or certification is required.

PART II: Information Cited


A. The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

Blumberg et al., Applicant

By: 
Alan W. Steele, M.D., Ph.D., Reg. No. 45,128
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600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

Docket No.: S1383.70011US00
Date: November 25, 2003
xNDDx

B. The Applicant hereby makes the following additional information of record in the above-identified application.

The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

Docket No.	Serial No.	Filing Date	Inventor
S1383.70006US00	10/215,298	08-08-2002	Blumberg et al.
S1383.70007US00	10/215,297	08-08-2002	Blumberg et al.
S1383.70010US00	10/435,608	05-09-2003	Blumberg et al.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. § 102.

FORM PTO-1449/A and B (Modified)				APPLICATION NO.: 10/622,108		ATTY. DOCKET NO.: S1383.70011US00			
				FILING DATE: July 17, 2003		CONFIRMATION NO.: 5945			
				APPLICANT: Blumberg et al.					
				GROUP ART UNIT: 1614		EXAMINER: Unknown			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT									
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FOREIGN PATENT DOCUMENTS (continued)

<input checked="" type="checkbox"/>	B2	WO	91/16074	A1	Medimmune, Inc.	10-31-1991	
	B3	WO	94/06476	A1	Immunex Corp.	03-31-1994	
<input checked="" type="checkbox"/>	B4	WO	96/22024	A1	The Brigham and Women's Hospital, Inc.	07-25-1996	
<input checked="" type="checkbox"/>	B5	WO	00/69913	A1	Lexigen Pharmaceuticals Corp.	11-23-2000	
<input checked="" type="checkbox"/>	B6	WO	01/03737	A1	Bolder Biotechnology, Inc.	01-18-2001	
<input checked="" type="checkbox"/>	B7	WO	02/43660	A2	Medimmune, Inc.	06-06-2002	
	B8	WO	03/077834	A2	The Brigham and Women's Hospital, Inc.	09-25-2003	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	AGNEW JE et al., Functional small airways defence in symptomless cigarette smokers. <i>Thorax</i> . 1986 Jul;41(7):524-30.	
	C2	BASELGA J et al., Recombinant humanized anti-HER2 antibody (Herceptin) enhances the antitumor activity of paclitaxel and doxorubicin against HER2/neu overexpressing human breast cancer xenografts. <i>Cancer Res</i> . 1998 Jul 1;58(13):2825-31.	
	C3	BROWN AR et al., Chamber for testing metered-dose propellant-driven aerosols of immunologically relevant proteins. <i>J Immunol Methods</i> . 1994 Dec 2;176(2):203-12.	
	C4	BURMEISTER WP et al., Crystal structure of the complex of rat neonatal Fc receptor with Fc. <i>Nature</i> . 1994 Nov 24;372(6504):379-83.	
	C5	BYRON PR, Prediction of drug residence times in regions of the human respiratory tract following aerosol inhalation. <i>J Pharm Sci</i> . 1986 May;75(5):433-8.	
	C6	FAHY JV et al., Effect of aerosolized anti-IgE (E25) on airway responses to inhaled allergen in asthmatic subjects. <i>Am J Respir Crit Care Med</i> . 1999 Sep;160(3):1023-7.	
	C7	FLEMING JS et al., Evaluation of the accuracy and precision of lung aerosol deposition measurements from single-photon emission computed tomography using simulation. <i>J Aerosol Med</i> . 2000 Fall;13(3):187-98.	
	C8	FRIEND PJ et al., Phase I study of an engineered aglycosylated humanized CD3 antibody in renal transplant rejection. <i>Transplantation</i> . 1999 Dec 15;68(11):1632-7.	
	C9	IMPACT-RSV STUDY GROUP, Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. <i>Pediatrics</i> . 1998 Sep;102(3 Pt 1):531-7.	
	C10	KNIGHT DM et al., Construction and initial characterization of a mouse-human chimeric anti-TNF antibody. <i>Mol Immunol</i> . 1993 Nov;30(16):1443-53.	
	C11	LALOR CB et al., Generation and characterization of aerosols for drug delivery to the lungs. In: <i>Inhalation Delivery of Therapeutic Peptides and Proteins</i> , Adjei AL and Gupta PK, eds., New York: Marcel Dekker, 1997, pp 235-276.	
	C12	MARTIN WL et al., Crystal structure at 2.8 Å of an FcRn/heterodimeric Fc complex: mechanism of pH-dependent binding. <i>Mol Cell</i> . 2001 Apr;7(4):867-77.	
	C13	NEWMAN SP et al., Understanding regional lung deposition data in gamma scintigraphy. <i>Respiratory Drug Delivery</i> . 1998;VI:9-15.	
	C14	OBER RJ et al., Differences in promiscuity for antibody-FcRn interactions across species: implications for therapeutic antibodies. <i>Int Immunol</i> . 2001 Dec;13(12):1551-9.	

FORM PTO-1449/A and B (Modified)		APPLICATION NO.: 10/622,108	ATTY. DOCKET NO.: S1383.70011US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: July 17, 2003	CONFIRMATION NO.: 5945
		APPLICANT: Blumberg et al.	
Sheet	1	of	3
		GROUP ART UNIT: 1614	EXAMINER: Unknown

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	4,678,751		Goeddel	07-07-1987
	A2	4,695,623		Stabinsky	11-22-1987
	A3	4,801,685		Goeddel et al.	01-31-1989
	A4	4,820,638		Swetly et al.	04-11-1989
	A5	4,897,471		Stabinsky	01-30-1990
	A6	4,921,699		DeChiara et al.	05-01-1990
	A7	4,973,479		Innis	11-27-1990
	A8	4,975,276		Innis	12-04-1990
	A9	5,098,703		Innis	03-24-1992
	A10	5,290,540		Prince et al.	03-01-1994
	A11	5,310,729		Lernhardt	05-10-1994
	A12	5,372,808		Blatt et al.	12-13-1994
	A13	5,541,293		Stabinsky	06-30-1996
	A14	5,605,690		Jacobs et al.	02-25-1997
	A15	5,661,009		Stabinsky	08-26-1997
	A16	5,723,125		Chang et al.	03-03-1998
	A17	5,758,637		Ivri et al.	06-02-1998
	A18	5,824,307		Johnson	10-20-1998
	A19	5,869,293		Pestka	02-09-1999
	A20	5,874,064		Edwards et al.	02-23-1999
	A21	5,938,117		Ivri	08-17-1999
	A22	5,980,884		Blatt et al.	11-09-1999
	A23	6,014,970		Ivri et al.	01-18-2000
	A24	6,019,968		Platz et al.	02-01-2000
	A25	6,030,613		Blumberg et al.	02-29-2000
	A26	6,085,740		Ivri et al.	07-11-2000
	A27	6,086,875		Blumberg et al.	07-11-2000
	A28	6,165,463		Platz et al.	12-26-2000
	A29	6,205,999	B1	Ivri et al.	03-27-2001
	A30	6,300,474	B1	Pestka	10-09-2001
	A31	6,423,344	B1	Platz et al.	07-23-2002
	A32	6,485,726	B1	Blumberg et al.	11-26-2002

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
✓	B1	WO	91/03553	A1	Immunex Corp.	03-21-1991	

FORM PTO-1449/A and B (Modified)		APPLICATION NO.: 10/622,108	ATTY. DOCKET NO.: S1383.70011US00
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		APPLICANT: Blumberg et al.	
Sheet	3	of	3
		GROUP ART UNIT: 1614	EXAMINER: Unknown

OTHER ART — NON PATENT LITERATURE DOCUMENTS (continued)

C15	PIAZZA FM et al., Immunotherapy of respiratory syncytial virus infection in cotton rats (Sigmodon fulviventer) using IgG in a small-particle aerosol. <i>J Infect Dis.</i> 1992 Dec;166(6):1422-4.		
C16	ROBINSON CR et al., Optimizing the stability of single-chain proteins by linker length and composition mutagenesis. <i>Proc. Natl. Acad. Sci. U.S.A.</i> 1998 May; 95:5929-35.		
C17	ROUTLEDGE EG et al., The effect of aglycosylation on the immunogenicity of a humanized therapeutic CD3 monoclonal antibody. <i>Transplantation.</i> 1995 Oct 27;60(8):847-53.		
C18	SHIELDS RL et al., High resolution mapping of the binding site on human IgG1 for Fc gamma RI, Fc gamma RII, Fc gamma RIII, and FcRn and design of IgG1 variants with improved binding to the Fc gamma R. <i>J Biol Chem.</i> 2001 Mar 2;276(9):6591-604. Epub 2000 Nov 28.		
C19	STORY CM et al., A major histocompatibility complex class I-like Fc receptor cloned from human placenta: possible role in transfer of immunoglobulin G from mother to fetus. <i>J Exp Med.</i> 1994 Dec 1;180(6):2377-81.		
C20	SWEENEY TD et al., Biopharmaceutics of immunoglobulin transport across lung epithelium. <i>Respiratory Drug Delivery.</i> 2000;VII:59-66.		
C21	WEST AP et al., Crystal structure and immunoglobulin G binding properties of the human major histocompatibility complex-related Fc receptor(.). <i>Biochemistry.</i> 2000 Aug 15;39(32):9698-708.		
C22	YU J et al., Pulmonary drug delivery: physiologic and mechanistic aspects. <i>Crit Rev Ther Drug Carrier Syst.</i> 1997;14(4):395-453.		

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]